



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,785	11/29/2001	Alex Azhayev	005416.00004	9129

22907 7590 04/23/2003

BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER

1639

DATE MAILED: 04/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/995,785

Applicant(s)
Azhayev et al

Examiner
Maurie G. Baker

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 5, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above, claim(s) 5-18, 20, 25-38, 40-44, 47, 48, and 50-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 21-24, 45, 46, and 49 is/are rejected.
- 7) ☒ Claim(s) 19 and 39 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 & 9 6) ☐ Other: _____

DETAILED ACTION

1. The Response filed February 5, 2003 (Paper No. 8) is acknowledged. No claims were amended, cancelled or added. Therefore, claims 1-63 are pending.

Election/Restriction

2. Applicant's election with traverse of Group I (claims 1-44 and 45-53 (in part)) in Paper No. 8 is acknowledged. The election of species is also acknowledged. The traversal is addressed below.

3. Applicant argues that the restriction should have been conducted under MPEP 803.02 and been confined only to an election of species. The examiner maintains that each of Groups I – VI are different inventions. That is, the inventions are differently classified and contain divergent subject matter.

4. As stated in the Restriction Requirement, the groups that describe these inventions each have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group could support a separate patent.

5. Thus, the different inventions would require different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper and is made FINAL.

6. Claims 45-53 (in part) and 54-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions; the requirement having been traversed in Paper No. 8.

7. Also, claims 5-18, 20, 25-38, 40-44, 47, 48 and 50-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being to allowable generic claim.

8. Therefore, claims 1-4, 19, 21-24, 39, 45, 46 and 49 are examined on the merits in this action.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-4, 21-24, 45, 46 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific supported compounds on pages 10-11 of the instant specification, does not reasonably provide enablement for all compounds (supported and unsupported) encompassed by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention when using the specific supported compounds on pages 10-11 of the instant specification; however, there is insufficient guidance as to how to make/use any compound (supported or unsupported) encompassed by the instant claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are drawn to supports and articles having a generic formula. The formula

encompasses a wide variety of compounds of varying structure and the claims (e.g. 45) also encompass unsupported compounds. This represents very broad scope. (3 and 5) The state of the prior art and the level of predictability in the art: Compounds that are used as linkers for solid supported synthesis were known at the time of filing; however, only limited numbers of such compounds were known and the specification gives *no* guidance to permit one of skill in the art to devise strategies for making and using any compound falling within the instant claims for such a purpose. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict their structures. The linkage chemistry to supports ("base material") of different structure as well as the linkage of oligonucleotides through different functionalities would be unpredictable. (4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. (6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only provided a very limited number of examples of supports and articles encompassed by the instant claims. Applicant's claimed scope of supports and articles represents only an invitation to experiment regarding possible compounds and their use. Specifically, the instant specification fails to identify that structure which is required for the claimed activity. (8) The quantity of experimentation needed to make or use the invention based on the content of

the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed supports/articles. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Status of Claims/Conclusion

11. No claims are allowed. However, claims 19 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
April 17, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER